

REMARKS

Claims 1-10, 57-75, 77-85, 87, and 99-103 are pending in the application. By this Response Claim 4 is hereby canceled. Claims 77 and 87 are amended. Attached hereto is a marked-up version titled, "Version with Markings To Show Changes Made".

Claim Rejection 35 U.S.C. § 102

35 U.S.C. § 102(b)

Claims 1, 2, 4, 8, 57, 58, 60, 66-68, 70, 77-79, 81, 85, 87, 99-103 stand rejected under 35 U.S.C. §102(b) as being anticipated over Forberg et al. (DD 138273), hereinafter *Forberg*. Applicant respectfully disagrees. References in this Reply refer to the translated summary provided. By this Reply, Claims 77 and 87 are amended and thus believed patentable over *Forberg*.

[A]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1982) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1984)) (emphasis added).

Regarding Claims 1, 2, 4, 8, 57, 58, 60, and 101-103 the presently claimed invention relates to a substantially dustless animal feed supplement including antibiotic granular fermentation solids.

As will be apparent, the present discussion is generally applicable to Claim 66 and to Claims 66-68, 70, with the obvious exception being that Claim 66 is drafted to a product by process format. Specifically, the product by process of claim is superior, in as much as, inexpensive fermentation solid are utilized rather than expensive purified/derivative material, as is described in *Forberg*. Additionally, *Forberg* fails to teach fermentation solids having the claimed activity. Therefore, the present invention as claimed in Claims 66-68 and 70 are patentable over *Forberg*. Removal of the pending rejection is requested and allowance solicited.

The presently claimed composition comprises an animal feed supplement including antibiotic granular fermentation solid. *Forberg* fails to describe the present invention. As the Federal Circuit noted, "An *anticipating* reference must describe the patented subject matter *with sufficient clarity and detail* to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the field of invention." *ATD Corp. v. Lydall, Inc.*, 48 USPQ.2d 1321,1328 (Fed. Cir. 1998) citing *In re Spada*, 15 USPQ.2d 1655, 1657 (Fed. Cir. 1990). emphasis added. In order to be an anticipating reference the art must teach all the limitations of the claimed invention. The *Forberg* reference does not teach the presently claimed particulate, substantially dustless supplement. In particular, *Forberg* describes a composition of matter wherein purified base, salt or a derivative of an antibiotic is included to achieve the desired potency. This is not the present invention.

As claimed, the present invention is an admixture of fermentation solids comprising an antibiotic and a potency standardizer. In contrast, *Forberg* is a composition of matter wherein purified base, salt or a derivative of an antibiotic is included. This is contrary to the claimed invention wherein fermentation solids are utilized to achieve the claimed antibiotic activity range. This argument is even further buttressed by the inclusion of product by process Claim 77 wherein the addition of antibiotic is specifically claimed (kindly note, claim 77 has been amended to more particularly point out and distinctly claim the present invention).

Forberg actually teaches a composition of matter including purified base, salt or a derivative of an antibiotic for achieving a desired antibiotic activity and not fermentation solid utilized to achieve the claimed activity between the range of about 10g/lb to about 300g/lb.

Moreover, *Forberg* fails teach a standardizer as utilized to generate a uniform premix, but, rather, *Forberg* teaches merely mixing the material with fodder for "compatibility" which is defined merely as "tolerance, in concentration". *Forberg*, Page 8.

From the foregoing therefore, it is believed that a *prima facie* case of anticipation has not been met inasmuch as *Forberg* fails to teach a fermentation solid having the claimed antibiotic activity. Removal of the pending rejection under 35 U.S.C. §102(b) to Claims 1, 2, 4, 8, 57, 58, 60, 66-68, 70, 77-79, 81, 85, 87, 99-103 is respectfully requested and allowance solicited.

Regarding Claims 77-79, 81, 85, 87, and 99-100, independent Claims 77, 87 are hereby amended to include the limitation wherein the additional antibiotic added is a fermentation product, therefore, Claims 77-79, 81, 85, 87, and 99-100 are patentably distinguishable from *Forberg*. *Forberg* merely teaches adding purified base, salt or a derivative of an antibiotic and not the present invention wherein the antibiotic activity is achieved by fermentation solids (as amended). Moreover, *Forberg* fails to teach the limitation of substantially uniform granules as recited in Claims 77 and 87. Removal of the pending rejection under 35 U.S.C. §102(b) is respectfully requested and allowance solicited.

Regarding the rejection of Claims 1-6, 8, 57-75, 87, 100-103 under 35 U.S.C. §102(b) as anticipated by *Klothen*, United States Patent Number 4,447,421, hereinafter *Klothen*. Applicant respectfully disagrees.

As argued previously, *Klothen* fails to teach the presently claimed invention. *Klothen* teaches combining a drug with a compressible carrier, followed by blending the mixture, compressing the mixture and granulating the composition. *Klothen*, Col. 1, lines 34-35. This is not the present invention, specifically, Claims 1 and 57 recite non-compacted compositions. With regard to Claims 77 and 87, *Klothen* fails to teach the introduction of

additional antibiotic. *Klothen* therefore fails to teach each and every limitation as is required to anticipate the present invention. Removal of the pending rejection under 35 U.S.C. §102(b) is respectfully requested and allowance solicited.

With regard to the Office's recitation of "The oil mineral and Soy oil, is shown of a non-compacted formulation g/Rb is 25." and "Thin meets claim 1." Applicant respectfully requests the Office clarify exactly what claims the Office is rejecting such that the Applicant may amend or offer arguments rebutting the Office's position. Specifically, *Klothen*, Table II appearing on Col. 7 does not include any reference to a component of (sic) 25 g/lb. If the Office is attempting to reject claims drawn to the inclusion of oil in the claimed composition, it is noted that *Klothen*, Table II does not include any reference to an amount of mineral oil included in a granular formulation. Removal of the pending rejection under 35 U.S.C. §102(b) is respectfully requested and allowance solicited.

Claim Rejection 35 U.S.C. § 103

35 U.S.C. § 103(a)

Claims 1-10, 57-75, 77-85, 87 and 99-103 stand rejected as obvious, 35 U.S.C. §103(a), as over *Klothern*, United States Patent Number 4,447,421, in view *King*, United States Patent Number 5,266,347, or in view of *Forberg*, DD 138273. The rejection is respectfully traversed.

When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to: (A) the claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) reasonable expectation of success is the standard with which obviousness is determined. *See MPEP* §

2141 and *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 220 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Moreover, to establish a *prima facie* case of obviousness “it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification.” *In re Lalu*, 747 F.2d 703, 223 USPQ 1257, 1258 (Fed. Cir. 1984). emphasis added.

This is not the case with *Klothen* in view of *Forberg*. *Klothen* teaches compacting the composition. *Forberg* fails to make up for the deficiency of *Klothen*. Particularly, *Forberg* does not teach the desirability of modifying *Klothen* to achieve the present invention. In fact, the fluid-bed generated product in *Forberg* is in stark contrast to the compacted drug and feed composition of *Klothen*. As the Federal Circuit has noted, obviousness cannot be established by combining the teaching of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so. *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984). Thus, the Office may not use the patent application as a basis for the motivation to combine or modify the prior art to arrive at the claimed invention, but, rather, must look to the references. The combination *Klothen* with *Forberg* fails to consider *Klothen* as a whole, and *Forberg* on the whole, as is required and noted above. Because, as argued previously, *Klothen* teaches merely adding a pre-prepared drug to inert diluent, such as whey solids. *Klothen* Col. 2, lines 15-33. In fact, *Klothen* teaches away from the present invention in its discussion of wet aggregate process. *Klothen* Col. 2, lines 1-14.

Additionally, *Forberg* does not teach the present invention wherein fermentation solids achieve the desired potency, but, instead merely adds additional (purified) antibiotics. This

is not the present invention. Rather, the present invention, as claimed Claim 1, utilizes fermentation solids to generate the desired concentration. Specifically, with regard to Claim 1 the use of purified material teaches away from the present invention because the addition of purified material goes away from the plain meaning of the claim. As the Federal Circuit has noted, "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." *M.P.E.P.* 2131.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Regarding the Office's rejection based on *Klothen* in view of *King*, *Klothen* teaches combining a drug with a diluent and compacting the mixture. Further, *Klothen* teaches that this process is superior in that the drug does not contaminate the milling equipment. Further, *Klothen* teaches that the blending and compaction steps are utilized to generate a standardized material. This is in contrast to the present invention wherein the material is not compacted. *King* does not correct the deficiencies of *Klothen*, rather, *King* on the whole specifically teaches that the concentration of antibiotic should be only sufficient to prevent fungal contamination.

Additionally, there is no motivation in either *Klothen* or *King* to combine the references. For argument sake, even if one were to combine *Klothen* and *King*, the combination would not result in the present invention. Rather, upon reading *Klothen*, one would be directed to a compaction process and away from a wet aggregate process. Upon reading *King* one would be directed to a wet aggregate, and away from increasing the concentration. The mere fact that the prior art may be modified in the manner suggested by the Office does not make the modification obvious unless the prior art suggested the desirability of the modification. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that "[o]ne cannot

use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992) quoting *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988).

Marked-Up Version of Amendment

Attached hereto is a marked-up version of the changes made to the specification and claims by the present amendment. The attached marked-up version is captioned “***VERSION WITH MARKINGS TO SHOW CHANGES MADE***”.

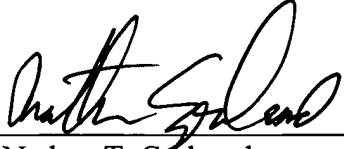
CONCLUSIONS

In light of the forgoing, reconsideration and allowance of the claims is earnestly solicited.

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Respectfully submitted,
Willis L. Winstrom,

Pennfield Oil Company

By 
Nathan T. Grebasch
Reg. No: 48,600

SUITER & ASSOCIATES PC
14301 FNB Parkway, Suite 220
Omaha, NE 68154-5299
Telephone: (402) 496-0300
Facsimile: (402) 496-0333

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend the claims as follows:

Kindly cancel claim 4

77. (Twice Amended) A particulate, substantially dustless animal feed supplement comprising fermentation solids comprising an antibiotic product of a fermentation process, said animal feed supplement prepared by:

culturing an organism producing an antibiotic in a fermentation medium to produce a fermentation broth comprising said antibiotic;

adding an additional quantity of said antibiotic, said additional quantity of antibiotic being obtained from a fermentation broth, to the fermentation broth to increase the antibiotic activity of said fermentation broth;

reducing said fermentation broth to obtain fermentation solids comprising said antibiotic;

drying said fermentation solids to produce a solid having a low moisture content; and

granulating said dried solid to produce granules having a substantially uniform particle size, said granulated fermentation solids having an antibiotic activity sufficient to ameliorate an antibacterial infection to treat an animal wherein the antibiotic activity is at least about 10g/lb to about 300 g/lb.

87. (Four times Amended) A particulate, substantially dustless animal feed supplement comprising fermentation solids comprising an antibiotic product of a fermentation process, said animal feed supplement prepared by:

providing fermentation solids, said fermentation solids having antibiotic activity;

adding an antibiotic to said fermentation solids, said added antibiotic being obtained from a fermentation broth;

drying said fermentation solids to produce a solid having a low moisture content; and
granulating said dry solid to produce granulated fermentation solids comprising granules having a substantially uniform particle size, said granulated fermentation solids having an antibiotic activity sufficient to ameliorate an antibacterial infection to treat an animal wherein the antibiotic activity is at least about 10g/lb to about 300 g/lb.